General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Plymouth Hospitals NHS Trust, Pharmacy Department, Derriford Hospital, Derriford Road, PLYMOUTH, Devon, PL6 8DH

Pharmacy reference: 1102686

Type of pharmacy: Hospital

Date of inspection: 10/11/2022

Pharmacy context

This is a pharmacy inside Derriford Hospital, in Plymouth, Devon and falls under the University Hospitals Plymouth NHS Trust. The pharmacy dispenses medicines to people who have been admitted to the hospital. This activity is regulated by the Care Quality Commission (CQC). The pharmacy holds a wholesale distribution authority (WDA) whose activity is regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA). The pharmacy is also registered with the General Pharmaceutical Council (GPhC) as it supplies medicines to several other organisations that are separate legal entities; this includes private organisations as well as community mental health trusts in the surrounding area. The inspection and resulting report only deal with activities associated with the pharmacy's GPhC registered activities.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Good practice	1.1	Excellent practice	The pharmacy team actively identifies and manages the risks associated with the pharmacy's services. The pharmacy has created and implemented several different internal governance processes for each of the different departments. This ensures a robust system of checks and balances are in place.
		1.2	Excellent practice	The pharmacy demonstrates a high level of commitment to reviewing and monitoring the safety and quality of its services. The pharmacy has strong governance processes in place which enable team members, managers and heads of departments to routinely record, review and feed back not just near misses and incidents but also other parameters which can affect the safety of the pharmacy's services. Suggestions and improvements are continuously made. And these working practices are embedded in the pharmacy's governance structure as well as the team's daily operations.
		1.3	Good practice	The pharmacy's services are provided by staff with clearly defined roles and clear lines of accountability. In addition to the standard operating procedures, there are verifiable processes in place for the service provided to external organisations, staff are clear on their roles and responsibilities and together with the managers, they ensure the pharmacy is run in a safe and effective way.
2. Staff	Standards met	2.1	Good practice	The pharmacy has enough suitably qualified and skilled staff to support the volume of work and provide a safe and effective service.
		2.2	Good practice	Members of the pharmacy team have the appropriate skills, qualifications and competence for their role and the tasks they undertake. Additional training provided to external drivers ensures that they are also suitably trained for this role.
		2.4	Good	The pharmacy has an embedded culture of

Principle	Principle finding	Exception standard reference	Notable practice	Why
			practice	openness, honesty, and learning. Team members are provided with training resources through the Trust's online learning platform. This helps ensure their skills and knowledge remain current.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	4.2	Good practice	The pharmacy's services are delivered efficiently using verifiable processes. The pharmacy provides a safe and reliable service to different organisations outside of the Trust.
		4.3	Good practice	The pharmacy routinely ensures that its medicines and medical devices are obtained from reputable sources, that they are safe and fit for purpose, stored and supplied to people safely as well as securely.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Good practice

Summary findings

The pharmacy provides a safe and effective service to external organisations. It identifies and manages risks very well. And it has robust internal processes in place to make things safer. The pharmacy team continually monitors the safety of its services by recording mistakes and learning from them. Team members are trained to protect the welfare of vulnerable people. The pharmacy protects people's private information appropriately. And it maintains its records as it should.

Inspector's evidence

The pharmacy held a range of electronic standard operating procedures (SOPs) to support the provision of its services. This included specific SOPs to cover the supply of medicines to the separate legal entities or organisations. This meant that there was guidance for the staff on the pharmacy's current process to follow when medicines were supplied to them. There were also service level agreements (SLA) between the pharmacy and the separate organisations to define the relationship and terms between them which were reviewed regularly. In addition, the pharmacy had a business continuity plan, this had been amended in response to the automated system failing (see Principle 5).

The SOPs ranged from being implemented or reviewed from 2019 to 2021. The SOPs were held on Q-Pulse software. This software enabled the person in charge of monitoring the SOPs to easily identify when SOPs required reviewing and which staff members needed to read or sign them. Reports could then be easily generated and sent to the appropriate manager(s) every week. This was then highlighted to action through the pharmacy's governance processes (see below). It was evident from the details seen that this process was being followed. In addition, staff could make change requests to SOPs through this system. The request was sent to the relevant person who approved or rejected the change. Staff understood their roles and responsibilities and they also had set tasks as well as accountabilities.

The pharmacy's internal processes to assemble and supply medicines to external organisations was very well-managed and run in a safe and effective way. The pharmacy identified and managed the risks associated with this service efficiently. It had many processes in place to help manage this (see below and Principle 4). There were clear segregated areas for each step in the process to take place. This included a separate room for pharmacists to clinically screen and check orders, a separate section to prepare controlled drugs (CDs) and cytotoxic medicines as well as segregated benches in the dispensary. The team also used colour coded trays to highlight urgency and supply to the different external organisations. The separate stations and coloured trays helped distinguish and keep the assembly of the pharmacy's internal workload separate to the supply for the external organisations. These working practices also helped minimise distractions, interruptions and errors.

The pharmacy had robust systems in place to identify, manage and monitor mistakes. Once medicines were assembled, if accuracy-checkers identified a near-miss mistake, a bespoke individual near-miss form was completed and placed inside a box that was clearly marked to hold these details. Errors were discussed with staff individually at the time but also collated as described below and fed into the pharmacy's governance structure so that regular reviews could take place. This involved the data being analysed by the pharmacy quality management group (PQMG) and reports compiled which were then conveyed to the team. Daily improvement huddles took place in the pharmacy where this information was fed back, and achievements or risks highlighted. Noticeboards around the dispensary and

pharmacy helped keep the team informed about their progress, highlighted areas for improvement and key measures for compliance. Staff could also input ways and make suggestions to improve processes. For example, laminated cards had been created in response to missing items which highlighted the need to check for certain things. Delivery times for the separate organisations had also been staggered to help reduce the influx of deliveries or pressure on the courier.

The pharmacy's governance structure was designed and carried out in a systematic way so that mistakes, incidents, good practice, learning, feedback or suggestions could be effectively highlighted from each different department and put into practice. The quality management departments included governance, clinical pharmacy, production, supply, high-cost drugs, commercial services, procurement and IT as well as clinical trials. The PQMG consisted of each of the different managers in their respective department(s), they compiled an internal report based on certain parameters obtained over the month. Monthly meetings were held to review the information compiled. This information was also fed back to the head of governance, operations and improvements who in turn, compiled an overall summary report. The summary report contained all the relevant details such as the total risks identified, the total number of incidents or serious mistakes, complaints, trends identified, staff training completed or outstanding, appraisals, sickness levels and details about drug alerts. The head of governance, operations and improvements also used this information to check, link and ensure that the pharmacy was continuing to operate in line with their internal strategy. And in turn, these reports were fed back to the Trust to show their overall compliance and commitment to improving patient safety.

The inspector was informed that due to another regulator's previous findings, the pharmacy had identified and developed these methods to improve their internal governance mechanisms. This system had been implemented approximately nine to ten months ago and involved not just identifying factors or relevant points but asking the question 'so what?'. Heads of departments were required to consider what to do about the data and how to make appropriate changes. Specific actions were implemented as a result and filtered down to the team through daily huddles, noticeboards and managers holding conversations. Consistent messages included improving turnaround times but balancing this with being quick and efficient without affecting the quality or safety of the service provided. The team looked to identify root causes of near misses and incidents, and staff were subsequently trained or re-trained on the pharmacy's internal processes.

The pharmacy's incident management processes were also suitable. Incidents for the separate organisations were managed by the logistics manager, investigated within 24 hours, logged on Datix and reviewed internally. Formal complaints were dealt with centrally by the Trust. There were different levels of service provided for each of the different organisations, some of whom had more informal processes in place. The level of formality varied with the type of service, the SLA, type of contract in place and the number of items provided. Concerns or incidents were raised through the contract process and feedback obtained through contract meetings that they held. In addition, the logistics manager held regular and, or daily discussions with the separate organisations. This helped ensure a seamless service was provided.

To protect people's private information, confidential waste was segregated and removed through the Trust's authorised carriers. Confidential information was contained within the pharmacy and the team regularly completed mandatory training on data protection. Staff were trained through the hospital's mandatory e-Learning to safeguard vulnerable people. This was to level 2, and they could access relevant contact details if escalation was required. Team members had checks made under the Disclosure and Barring Service (DBS). Additional training was also provided to the couriers (see Principle 2).

A sample of registers seen for controlled drugs (CDs) were maintained in line with statutory requirements. On checking a random selection of CDs, quantities held matched balance entries in corresponding registers. Balances for CDs were routinely checked, and details seen documented. This included checking the actual balance against the electronic and documented records. There had been no unlicensed medicines provided, supplies made against private prescriptions or emergency supplies required for the separate legal entities. The pharmacy's professional indemnity insurance was through the Trust and electronic daily records about the minimum and maximum temperatures for the medical fridges were maintained through a particular integrated software. This helped verify that medicines were being appropriately stored here. The documented RP record was complete although the records were made up of loose sheets. This meant that the information could potentially be lost, or records inserted inadvertently. An incorrect responsible pharmacist notice was on display. This was discussed at the time and is a legal requirement to provide information about the pharmacist in charge of operational activities on the day.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload appropriately. Members of the pharmacy team have a range of skills and experience. The pharmacy provides additional resources to help keep their skills and knowledge up to date. And external drivers from the courier service are also appropriately trained.

Inspector's evidence

The pharmacy employed around 170 members of staff, this included the superintendent pharmacist, 35 pharmacists, around 30 pharmacy technicians, assistant technical officers, admin staff and various managers, heads or managers of departments, associate directors or directors. This meant that there were plenty of staff to manage the pharmacy's workload. The inspector dealt predominantly with some of the staff, including one of the lead pharmacists, the associate director of operations and the logistics manager. The latter was a registered pharmacy technician and a long-standing member of staff. All team members were wearing identity cards with their names. The team consisted of staff with different levels of experience and training.

Members of the pharmacy team were appropriately trained through accredited routes or were suitably supervised. This included drivers from the external courier service who were provided with in-house training on medicinal products. This helped ensure they were appropriately trained to provide this service. Pharmacy staff were provided with ongoing and routine training through mandatory e-learning, which was delivered through the Trust and refreshed annually. Examples included training on data protection, safeguarding, cytotoxic medicines and updates on SOPs. Completion of mandatory, refresher training and updates were monitored by department heads and managers. The logistics report compiled by the logistics manager captured all this relevant data, including details of the latter. Audits were also carried out regularly. Formal appraisals for staff were conducted annually and the quality of them checked.

It was apparent that the pharmacy had increasingly invested in its staff. Different people from within the department or hospital had been promoted or recruited to manage different teams within the pharmacy, and they reported to the chief pharmacist. The senior leadership group held regular team meetings, where the pharmacy's internal strategy was shared in order to align this with the Trust. Individual improvement and patient safety projects were also ongoing.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises provide an adequate environment to deliver its services from. The pharmacy is clean and tidy. It has plenty of space for the team to work in safely. And it is secure from unauthorised access.

Inspector's evidence

The pharmacy premises consisted of several areas. This included a spacious dispensary, a separate section where pharmacists who undertook clinical checks were based, distribution and designated areas for stock which included the automated dispensing system (robot) as well as offices, the logistics and transport office, the clinical trials and aseptic unit. There was plenty of space to carry out dispensing activities and all areas seen were kept clear of clutter. The transport office was organised and consisted of different areas to store deliveries for different organisations. There was also a separate section in here to process orders under the pharmacy's WDA. The pharmacy was professional in its appearance, clean and tidy. It was also suitably lit and appropriately ventilated. The pharmacy was suitably secured against unauthorised access.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy's working practices are safe and effective. This includes ensuring the risks associated with the delivery service are well managed. The pharmacy obtains its medicines from reputable sources, it stores and manages them well. And it keeps appropriate records to verify how its services are being run.

Inspector's evidence

The pharmacy was located on Level 5 of the hospital and signposted. There were lifts and stairs to this floor, wide corridors leading to the pharmacy as well as clear, open space outside the hatch. This helped people with restricted mobility to easily access the pharmacy's services. People approaching the pharmacy from inside the hospital could access services from the front hatch. There were a few seats available for people who wished to wait and a few car parks around the hospital. If any of the outside organisations required medicines outside of the pharmacy's opening hours, they could contact the on-call pharmacist.

Prescriptions for medicines required by the separate organisations were received electronically, printed and then clinically screened before being assembled. During the dispensing process, colour coded trays were used to hold prescriptions and medicines. This helped to prevent any inadvertent transfer of items and identify medicines that were for these organisations. Dispensing audit trails were used by the team to identify staff involved during the different processes. Medicines that required refrigeration or CDs were flagged and the latter were processed in a different space. Only authorised individuals could enter this area. Once assembled, CDs were placed inside sealed bags. After prescriptions were bagged and sealed, they were taken to the logistics team to be processed for delivery.

Medicines were delivered to the separate organisations by authorised couriers (City Sprint). The logistics manager explained that a bespoke service had been set up and was provided by this courier. The pharmacy had kept the appropriate records to verify this service. Medicines requiring refrigeration or CDs were highlighted and specific boxes for these medicines were used to transport them in addition to the sealed bags. This helped maintain ambient temperature control. Daily inspections of the van(s) used for delivery also took place by the team. This was to ensure that the van contained no other items and was clean and tidy. In addition, team members supervised transport of the bags into the van(s). As highlighted under Principle 1, the pharmacy staggered the times for deliveries and couriers. This helped reduce the risk of medicines not being collected or mixing up deliveries. Processes were also in place for failed deliveries. In this situation, drivers contacted the logistics team, medicines were not left unattended, and they were brought back to the pharmacy within the office's working hours (up until 8pm). Specific and tailored advice was provided if the out of hours team was contacted and failed CD deliveries were managed by the on-call pharmacist.

The pharmacy also supplied some people's medicines inside multi-compartment compliance packs for some of the external organisations after a need had been identified for this. Specific records were kept for this purpose. Any queries were checked, and the records were updated accordingly. All medicines were removed from their packaging before being placed inside them. Descriptions of the medicines inside the compliance packs were provided and patient information leaflets (PILs) were routinely supplied. Compliance packs were not left unsealed overnight. Any medicines with variable dosing (such

as warfarin) were not supplied inside the compliance packs and formulations were changed if appropriate.

The pharmacy could request access to and check blood test results for people if required. This included people prescribed higher-risk medicines. In addition to the clinical checks made in the pharmacy, the lead pharmacist explained that besides the professional conversations held between them, generally, pharmacists or health care professionals in the different organisations were responsible for providing advice and counselling. Additional support was provided however, if or when it was required. This included access to the pharmacy's on-call services.

Medicines were stored in an ordered manner on shelves and predominantly inside the robot. The pharmacy obtained its medicines from multiple and reputable wholesalers such as AAH, Alliance Healthcare and Phoenix. The team date-checked medicines for expiry regularly, using the robot's inventory and kept records to verify this. Short-dated medicines were identified. Liquid medicines with short stability were marked with the date upon which they were opened. The fridges were operating at appropriate temperatures. The pharmacy had procedures in place to store and destroy medicines returned by the wards for disposal, this including effectively highlighting them. But the team did not accept medicines requiring disposal from external organisations. Drug alerts and product recalls were received via the pharmacy's internal systems, stock was checked, and action taken as necessary. The team kept a full audit trail to verify this process.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has a suitable range of equipment and facilities. This helps to provide its services safely. It has back-up processes in place in case the equipment fails. And its equipment is clean

Inspector's evidence

The pharmacy had the range of equipment and facilities required. This included current reference sources, clean, crown stamped conical measures for liquid medicines and a robot. The inspector was told that the robot frequently broke down, it was due to be refurbished and eventually replaced but regular and quick maintenance or service took place when needed. When this broke down, this slowed the team, but the stock could still be removed physically from here and used for dispensing. The pharmacy also had a generator in the event of a power failure. The pharmacists could use online reference databases as well as the medicines information department based at the hospital if required. The dispensary sink used to reconstitute medicines was clean, there was hot and cold running water available here with hand wash. The medical fridges were operating appropriately. The CD cabinets were secured in line with the requirements. Computer terminals were positioned in a manner that prevented unauthorised access.

What do the summary findings for each principle mean?

Finding	Meaning
✔ Excellent practice	The pharmacy demonstrates innovation in the way it delivers pharmacy services which benefit the health needs of the local community, as well as performing well against the standards.
✔ Good practice	The pharmacy performs well against most of the standards and can demonstrate positive outcomes for patients from the way it delivers pharmacy services.
✔ Standards met	The pharmacy meets all the standards.
Standards not all met	The pharmacy has not met one or more standards.